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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,327	05/15/2002	Jay M Meythaler	UAB-15102/22	3596

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EXAMINER
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TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/04/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/049,327

Applicant(s)  
Meythaler et al

Examiner  
R.S. Travers J.D., Ph.D.

Art Unit  
1617



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-35 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

Art Unit:

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7 and 29-35, drawn to treating neuro-trauma by therapeutically administering therapeutic compositions containing various non-steroidal anti-inflammatory drugs (NSAID's).

II. Claims 8-16, drawn to treating diffuse axonal injury by therapeutically administering therapeutic compositions containing various omega conotoxin compounds

III. Claims 17-21, drawn to treating diffuse axonal injury by therapeutically administering therapeutic compositions containing various omega conotoxins concomitantly with non-steroidal anti-inflammatory drugs (NSAID's).

IV. Claims 22-28, drawn to treating pain generally by therapeutically administering therapeutic compositions containing various non-steroidal anti-inflammatory drugs (NSAID's).

The above delineated inventions differ as distinct therapeutic compositions employed in patentably distinct therapeutic methods. The grouped inventions are patentably distinct, a reference which would anticipate, or make obvious, any invention from groups I-IV would not necessarily obviate, or anticipate, the inventions in any other group. The searches are not co-inclusive as indicated by the diverse nature of

Art Unit:

the subject matter. Those proposed inventions recited herein are only linked by the presented specification; with each invention requiring separate, distinct search, and consideration. One skilled in the art would readily practice the invention of one of the above groups with out infringing and/or practicing the invention of another group. The subject matter is unique and has acquired a separate status in the art and is fully capable of supporting separate patents. For the foregoing reasons restriction is proper for examination purposes.

The instant application was filed under 35 USC 371, requiring restriction by unity of invention. The authority for this restriction practice is found in 37 CFR 1.499. To restrict a case filed under 35 USC 371, the Examiner need not consider the burden posed by examining additional inventions; although such burden is present in the instant case. Examiner notes the instant claims fail to contain, either maladies linked by an etiology, or medicaments specifically adapted to those therapies herein envisioned. Thus, those inventions herein recited fail to embody any special technological features to link the separate inventions herein claimed. Failing to embody a specific unifying technological feature, the presented claims lack unity of invention, and are properly subject to restriction.

Patent Cooperation Rules (PCT) Rules 13.1 and 13.2 permit in a single application only one invention. Thus, an application lacking unity of invention, and

Art Unit:

presenting more than one invention, as in the instant case, is appropriately restricted for lack of unity.

The grouped inventions are patentably distinct, a reference which would anticipate, or make obvious, any invention from groups I-V would not necessarily obviate, or anticipate, the inventions in any other group. The searches are not co-inclusive as indicated by the diverse nature of the subject matter, thus, would represent an undue burden on Examiner. One skilled in the art would readily practice the invention of one of the above groups without infringing and or practicing the invention of another group. The subject matter is unique and has acquired a separate status in the art and is fully capable of supporting separate patents. For the foregoing reasons restriction is proper for examination purposes.

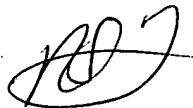
Claims contained in Groups I-IV are directed to patentably distinct inventions. Applicants are required under 37 CFR 1.499 to elect a distinct therapeutic method, even though this requirement is traversed.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variations or clearly admit on the record that this is the case. In either instance, if Examiner finds one of the inventions unpatentable over

Art Unit:

the prior art, the evidence may be used in a rejection under 35 USC 103 of the other invention.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

A handwritten signature in black ink, appearing to read 'RT', is positioned above the printed name.

**Russell Travers J.D., Ph.D.**  
**Primary Examiner**  
**Art Unit 1617**